

REMARKS

In the present Amendment, Claim 1 has been cancelled since it is the same as Claim 33. Claim 33 has been amended to recite that the polymerization process is a polymerization process for forming a compound which is a conjugate of a polymer and a biologically active moiety. Section 112 support for the amendment is found, for example, at page 16, lines 19-21 and in the abstract of the specification. In addition, "Y" appears in formula I and in formula V in Claim 33. To avoid ambiguity, the second Y (the Y in formula V) has been changed to Y¹, and the claims have been amended accordingly. The specification and formula V in Claim 56 have been amended similarly. Claims 34 and 36 have been amended in response to the §112 rejection. Claim 35 has been amended to depend from Claim 34. Claim 69 has been amended to correct a typographical error. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, Claims 33-78 will be pending, of which Claims 38-40, 56-63, 65, 66 and 71-78 are withdrawn from consideration.

Initially, the Examiner is respectfully requested to acknowledge Applicant's claim for foreign priority and receipt of the certified copy of the priority document.

Claims 1, 33-37, 41-55, 64 and 67-70 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 34 and 36 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The claims have been amended to address the Examiner's concern. Accordingly, withdrawal of the §112 rejections is respectfully requested.

Claims 1, 33-35, 46-53, 64 and 68-70 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Haddleton (U.S. 6,310,149). Claims 1, 33-35, 46-53, 64 and 68-70 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Haddleton.

The above two rejections should be withdrawn because Haddleton does not disclose or render obvious the present invention.

The Examiner has referred to the admitted prior art in the present specification at paragraph [0131] of the published application. Applicant believes that this is page 20, line 5 of the specification. Perhaps the wording there is confusing. However, what was disclosed there is that the cholesteryl compound is used as an initiator in an atom transfer radical polymerisation process using copper (I) bromide and the defined imine ligand, which is described in Haddleton. Haddleton does not disclose that 2-methacryloyloxy-2'-ethyltrimethylammoniumphosphate inner salt (MPC) monomer is used as the monomer for the atom transfer radical polymerisation. Applicant believes that the wording of the Example is clear, in that the features mentioned before "US-A-6,310,149" are known, while those mentioned after the Patent number are the novel features of the present invention.

The Examiner alleges that Haddleton describes polymerising zwitterionic monomer such as the MPC. The Examiner does not point to any particular portion of Haddleton.

However, in fact, Haddleton does not describe polymerisation of such monomers. MPC is not mentioned as a species in Haddleton, nor is any zwitterionic monomer, for instance in the passage describing the monomers which may be used at column 11, line 55 to column 12, line 16 of Haddleton. Applicant has reviewed all the passages cited by the Examiner at page 4 of the Action, but none of them mentions a zwitterionic monomer, nor specifically MPC.

In view of the above, reconsideration and withdrawal of the §102 rejections based on Haddleton are respectfully requested.

Claims 1, 33-37, 41-43, 46-55, and 67-70 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Haddleton in view of Davies et al (WO 01/27209).

This rejection should be withdrawn because Haddleton and Davies et al do not disclose or render obvious the present invention, either alone or in combination.

Davies et al is cited as teaching that polymers derived from MPC inner salts are capable of binding biologically active agents (abstract; page 1, lines 2-3; and page 10, lines 18-21).

As discussed above, Haddleton does not teach polymerisation of MPC or other zwitterionic monomers. Davies et al teaches polymers derived from MPC, however, they are not produced by the atom transfer radical polymerisation process of Haddleton. Also, Davies et al does not teach a polymerisation in which an initiator component becomes part of the polymer. Nor does Davies et al describe polymerisation in which the initiator has a biologically active moiety.

In view of the above, reconsideration and withdrawal of the §103(a) rejection based on Haddleton in view of Davies et al are respectfully requested.

Claims 1, 33-37, 41-55, 64 and 67-70 have been rejected for obviousness-type double patenting as being unpatentable over Claims 1-28 of U.S. Patent No. 6,562,330 in view of Haddleton.

This rejection should be withdrawn because the present claims are not obvious over Claims 1-28 of the '330 patent for the following reasons.

The claims of the '330 patent do not recite atom transfer radical polymerisation type processes or polymerisation involving initiators having biologically active moieties. The

polymerisation method used in the '330 patent is entirely different from the very special type of polymerisation describe by Haddleton. There is nothing in either document to suggest that the initiator of Haddleton could be used to polymerise the monomers described in the '330 patent. In the '330 patent, polymerisation is initiated with an initiator in a process involving entirely different reaction kinetics from those of the atom transfer radical polymerisation type process of Haddleton.

Claims 1, 33-35, 46-53, 64 and 68-70 have been rejected for obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent No. 6,852,816 in view of Haddleton.

Claims 1, 33-37, 41-55, 64 and 67-70 have been rejected for obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent No. 6,852,816 in view of Haddleton and further in view of Davies et al.

The above two rejections should be withdrawn because the present claims are not obvious over Claims 1-39 of the '816 patent for the following reasons.

The present claims are not obvious over the claims of the '816 patent, because there is no disclosure in the '816 patent of using an initiator with any biologically active substituent. The use of an initiator with a biologically active substituent for the types of monomer polymerised in the U.S. '816 patent is, on the other hand, not obvious. There is nothing to render it obvious to replace the initiators described in the '816 patent with the cholesteryl initiator disclosed by Haddleton.

Claims 1, 33-37, 41-55, 64 and 67-70 have been *provisionally* rejected for obviousness-type double patenting as being unpatentable over Claims 1, 23 and 36-43 of co-pending Application No. 10/506,814 in view of Haddleton.

Claims 1, 33-37, 41-55, 64 and 67-70 have been *provisionally* rejected for obviousness-type double patenting as being unpatentable over Claims 29-44 of co-pending Application No. 10/544,113.


Claims 1, 33-37, 41-55, 64 and 67-70 have been *provisionally* rejected for obviousness-type double patenting as being unpatentable over Claims 44-100 of co-pending Application No. 10/542,333.

The above three provisional double patenting rejections should be withdrawn because the respective claims of the co-pending applications do not recite an initiator with any biologically active substituent.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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CUSTOMER NUMBER

Date: March 12, 2009